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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 05-004-1]

RIN 0579-AB93

Importation of Whole Cuts of Boneless Beef from Japan

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations governing the importation of meat and other edible animal products by allowing, under certain conditions, the importation of whole cuts of boneless beef from Japan. We are proposing this action in response to a request from the Government of Japan and after conducting an analysis of the risk that indicates that such beef can be safely imported from Japan under the conditions described in this proposal.

DATES: We will consider all comments that we receive on or before September 19, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to http://www.epa.gov/feddocket to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the "View Open APHIS Dockets" link to locate this document.

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 05-004-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 05-004-1.
- Federal eRulemaking Portal: Go to http://www.regulations.gov and follow the instructions for locating this docket and submitting comments.

Other Information: All comments submitted in response to this proposal, as well as analyses for this proposal, are available at the EDOCKET web site shown above and our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming. You may also view APHIS documents published in the Federal Register and related information on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Director, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the Department) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. The

regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE), a chronic degenerative disease affecting the central nervous system of cattle.

Section 94.18 of the regulations prohibits or restricts the importation into the United States of meat and certain other edible products due to BSE. Paragraph (a)(1) of § 94.18 lists regions in which BSE is known to exist. Paragraph (a)(2) of § 94.18 lists regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance for BSE. Paragraph (a)(3) of § 94.18 lists regions that present a minimal risk of introducing BSE into the United States. Except for certain controlled transit movements, § 94.18(b) prohibits the importation of meat, meat products, and most other edible products of ruminants that have been in any region listed in § 94.18(a)(1) or (a)(2) and restricts the importation of those commodities from any region listed in § 94.18(a)(3).

In an interim rule published in the Federal Register on October 16, 2001 (66 FR 52483-52484, Docket No. 01-094-1), and effective on September 10, 2001, we amended the regulations by adding Japan to the list in § 94.18(a)(1) of regions where BSE exists. That action was prompted by the confirmation of BSE in a native-born animal in Japan. The effect of the interim rule was to prohibit the importation of ruminants that have been in Japan, as well as meat, meat products, and most other products and byproducts of ruminants that have been in Japan.

Immediately following the detection of the BSE-infected cow, the Government of Japan initiated an epidemiological investigation and took a series of measures to detect and control BSE in Japan, including measures to ensure that tissues that have the potential to carry infectious levels of the BSE agent are removed from cattle at slaughter, a ban on the feeding of mammalian protein to ruminants is in place, and increase BSE surveillance.

The Government of Japan has requested that APHIS consider allowing the resumption of trade in beef from Japan to the United States. Prior to the 2001 ban on the importation of ruminants and ruminant products from Japan, Japan primarily exported to the United States boneless cuts of beef from cattle born raised and slaughtered in Japan. Therefore, in response to Japan's request, we considered allowing the importation of whole cuts of boneless beef derived from cattle that were born, raised, and slaughtered in Japan and analyzed the animal health risks associated with that product.[1] For a consideration of the risks to human health, we consulted with the Food Safety and Inspection Service (FSIS) of USDA, which is the public health agency that is responsible for ensuring the food safety of this product. The risk analysis is available on EDOCKET and in the APHIS reading room. (Information on accessing EDOCKET as well as the location and hours of the APHIS reading room may be found at the beginning of this document under ADDRESSES.) You may also request paper copies of the analysis by calling or writing the person listed under FOR FURTHER INFORMATION CONTACT. Please refer to Docket No. 05-004-1 when requesting copies of the risk analysis.

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[1] In this proposal, we use the term "whole cuts of boneless beef" to refer to meat derived from the skeletal muscle of a bovine carcass, excluding all parts of the animal's head and diaphragm. Meat that has been ground, flaked, shaved, or otherwise processed, comminuted, or mechanically separated would not be whole cuts of boneless beef.

Under the Animal Health Protection Act (7 U.S.C. 8301 et seq.), the Secretary of Agriculture may prohibit the importation of any animal or article if the Secretary determines that the prohibition is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. The Secretary has determined that it is not necessary to continue to prohibit the importation of whole cuts of boneless beef derived from cattle that were born, raised, and slaughtered in Japan, provided that the conditions described in this proposal are met. This determination is based on a number of factors, including research on BSE and the risk analysis prepared for this rulemaking.

In this proposed rule, we will first provide some background on BSE. Next, we discuss the scientific evidence that provides a basis for the proposed conditions, then discuss the proposed conditions in further detail. Finally, we will briefly discuss the proposed conditions as they relate to international guidelines on BSE.

Bovine Spongiform Encephalopathy

BSE is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. However, the distribution of infectivity in the body of the animal and mode of transmission differ according to the species and TSE agent. In addition to BSE, TSEs include, among other diseases, scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and variant Creutzfeldt-Jakob disease in humans.

The agent that causes BSE has yet to be fully characterized. The theory that is most accepted in the international scientific community is that the agent is an abnormal form of a

normal protein known as cellular prion protein. The BSE agent does not evoke a traditional immune response or inflammatory reaction in host animals. BSE is confirmed by post-mortem microscopic examination of an animal's brain tissue or by detection of the abnormal form of the prion protein in an animal's brain tissues. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is resistant to heat and to normal sterilization processes. BSE is not a contagious disease; according to internationally accepted research, the only confirmed, natural route of transmission of BSE in cattle is the consumption of animal feed containing protein from ruminants infected with BSE.

BSE was first documented in the United Kingdom in 1986 and has since been confirmed in native-born cattle in 22 European countries in addition to the United Kingdom, and in some non-European countries, including Japan, Israel, Canada, and the United States. Since November 1986, there have been more than 186,000 confirmed cases of BSE in cattle worldwide. As of July 2005, Japan had reported a total of 20 cases of BSE, including the initial case of BSE in September 2001 and two cases that are currently under further investigation.[2]

In the United States, there have been two confirmed cases of BSE, one an imported cow and one a native cow. The first case of BSE in the United States was identified in a dairy cow in Washington State on December 23, 2003. The epidemiological investigation and DNA test results confirmed that the infected cow was not indigenous to the United States, but rather was born and most likely became infected in Alberta, Canada, before Canada's 1997 implementation of a ban on feeding most mammalian protein to ruminants, which prevents the use of most

[2] See the risk analysis for further information.

mammalian protein in cattle feed. The second case of BSE in the United States was confirmed in an approximately 12-year-old beef cow in Texas on June 29, 2005. This animal was born well before the United States instituted a mammalian-to-ruminant feed ban in August 1997.

Variant Creutzfeldt-Jakob disease (vCJD), a chronic and fatal neurodegenerative disease of humans, has been linked since 1996 through epidemiological, neuropathological, and experimental data to exposure to the BSE agent, most likely through consumption of cattle products contaminated with the agent before BSE control measures were in place. To date, approximately 170 probable and confirmed cases of vCJD have been identified worldwide. The majority of these cases have either been identified in the United Kingdom or were linked to exposure that occurred in the United Kingdom, and all cases have been linked to exposure in countries with native cases of BSE. Some studies estimate that more than 1 million cattle may have been infected with BSE throughout the epidemic in the United Kingdom. This number of infected cattle could have introduced a significant amount of infectivity into the human food supply. Yet, the low number of cases of vCJD identified to date indicates that there is a substantial species barrier that protects humans from widespread illness due to exposure to the BSE agent.

Factors Considered in the Development of the Proposed Import Conditions

BSE Infectivity

Examination of naturally-occurring BSE cases and extensive well-controlled BSE challenge studies have clearly demonstrated that the primary site for BSE accumulation in cattle is the central nervous system (brain, spinal cord, trigeminal ganglia, dorsal root ganglia (DRG),

and eye).[3] Small amounts of BSE infectivity accumulate in the distal ileum, and only trace amounts have been found in tonsil samples. Importantly, BSE studies in cattle to date have not detected infectivity in any other tissues than those listed above. These studies also have found that the level of infectious agent in these tissues varies with the age of the animal, with the highest levels of infectivity detected in the brain and spinal cord at the end stages of disease.

BSE has a long incubation period. Research demonstrates that the incubation period for BSE in cattle is linked to the infectious dose received–i.e., the larger the infectious dose received, the shorter the incubation period. Cattle typically develop clinical signs after an average incubation of 4 to 6 years post-infection.

This research on BSE has been used to develop effective, proven strategies for removal of these tissues from animals of appropriate age so that these tissues do not enter the food chain. In the United States, the FSIS regulations contained in 9 CFR 310.22 designate the brain, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), DRG, trigeminal ganglia, skull, and eyes of cattle 30 months of age and older, and the tonsils and the distal ileum of cattle of any age as SRMs and prohibit their use as human food.[4]

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[3] DRG are clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column. Trigeminal ganglia are clusters of nerve cells connected to the brain that lie close to the exterior of the skull.

[4] The skull and vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) of cattle 30 months of age and older were designated as SRMs in the FSIS regulations because they contain high-risk tissues such as the brain and spinal cord.

BSE infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with BSE at any stage of the disease. Studies performed using TSEs other than BSE in non-bovine animals have detected prions in muscle tissue. However, the international scientific community largely considers that these studies cannot be directly extrapolated to BSE in cattle because of the significant interactions between the host species and the prion strain involved.

Pathogenesis studies of naturally and experimentally infected cattle have not detected BSE infectivity in blood. However, transmission of BSE was demonstrated in sheep that received a transfusion of a large volume of blood drawn from other sheep that were experimentally infected with the BSE agent. The United Kingdom's Department for Environment, Food and Rural Affairs' Spongiform Encephalopathy Advisory Committee (SEAC) and the European Commission's Scientific Steering Committee (SSC), which are scientific advisory committees, evaluated the implication of this finding in relation to food safety.[5] The SEAC concluded that the finding did not represent grounds for recommending any changes to the current control measures for BSE. The SSC determined that the research results do not support the hypothesis that bovine blood or muscle meat constitute a risk to human health.[6]

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[5] Spongiform Encephalopathy Advisory Committee, Oct 19, 2000, Summary of SEAC Committee Meeting 29 September 2000. Available at http://www.defra.gov.uk/news/seac/seac500.htm.

[6] European Commission Scientific Steering Committee. "The Implications of the Recent Papers on Transmission of BSE by Blood Transfusion in Sheep (Houston et al, 2000); Hunter et al, 2002), Adopted by the SSC at its Meeting of 12-13 September." Available at http://europa.eu.int/comm/food/fs/sc/ssc/out280_en.pdf.

Based on this information, APHIS concludes that whole cuts of boneless beef do not present a BSE risk, provided that certain measures are in place to avoid contamination of the beef with potentially infectious tissues.

BSE Risk Factors for Whole Cuts of Boneless Beef

The most significant risk management strategy for ensuring the safety of whole cuts of boneless beef is the prevention of cross-contamination of the beef with SRMs during stunning and slaughter of the animal. Control measures that prevent contamination of such beef involve the establishment of procedures for the removal of SRMs, prohibitions on air-injection stunning and pithing, and splitting of carcasses. These potential pathways for contamination and the control measures that prevent contamination are described in detail in the risk analysis for this rulemaking.

SRM Removal. Research has demonstrated that SRMs from infected cattle may contain BSE infectivity. Because infectivity has not been demonstrated in muscle tissue, the most important mitigation measure for whole cuts of boneless beef is the careful removal and segregation of SRMs. Removal of SRMs in a manner that avoids contamination of the beef with SRMs minimizes the risk of exposure to materials that have been demonstrated to contain the BSE agent in cattle.

Air-injection Stunning. Generally speaking, there are two types of captive bolt stunners used worldwide on livestock at slaughter: penetrative and non-penetrative. Penetrative captive bolt stun guns render cattle unconscious, quickly and painlessly, prior to slaughter. Penetrative captive bolt stun guns have steel bolts, powered by either compressed air or a blank cartridge, which are driven into the animal's brain. Captive bolt stun guns built or modified to inject

compressed air into the cranium of cattle have been shown to force pieces of brain and other CNS tissue into the circulatory system of stunned cattle, thereby potentially spreading CNS tissue throughout the carcass. These studies prompted a prohibition on the use of air-injection stunning in the United States.[7] Other types of penetrative captive bolt stunners include pneumatically operated stunners that do not inject air and standard cartridge-fired captive bolt stunners. In general, studies do not indicate that these other types of penetrative captive bolt stunners pose a significant risk of causing CNS tissue to be forced into the circulatory system of cattle.

Pithing. Pithing involves the insertion of an elongated rod-shaped instrument into the cranial cavity of a stunned animal to further lacerate the CNS tissue. This process could cause dissemination of CNS tissue throughout the body of the animal during slaughter. This stunning method is banned in the European Union and has never been used in the United States.

Carcass Splitting. During processing, infectivity could contaminate muscle tissue in cattle if tissue debris, specifically spinal cord, accumulates in the carcass splitting saw and is transferred to subsequent carcasses. This potential means of cross-contamination is very unlikely, however, provided that the SRMs of the cattle are effectively removed and cleaning and sanitation procedures that reduce the likelihood of cross-contamination from splitting saws are in place.

[7] See FSIS' interim final rule entitled, "Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter" (Docket No. 01-033IF, 69 FR 1885-1891), published on January 12, 2004, for further information.

To mitigate these risk factors, we are proposing to require the conditions discussed below to ensure that whole cuts of boneless beef exported to the United States from Japan are free of BSE contamination.

Proposed Import Conditions

This proposal would allow the importation of whole cuts of boneless beef that are derived from cattle born, raised, and slaughtered in Japan, provided that the following conditions have been met:

- The beef is prepared in an establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the regulations in 9 CFR 327.2 and the beef meets all other applicable requirements of the FMIA and regulations thereunder (9 CFR chapter III), including the requirements for removal of specified risk materials (SRMs) and the prohibition on the use of air-injection stunning devices prior to slaughter on cattle from which the beef is derived.
- The beef is derived from cattle that were not subjected to a pithing process at slaughter.
- An authorized veterinary official of the Government of Japan certifies on an original certificate that the above conditions have been met.

Following is a further description of and rationale for each of these proposed conditions.

Establishment Eligibility

This proposal would require that the beef be prepared in an establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the regulations in 9 CFR 327.2.

As required under the FMIA, FSIS ensures that imported meat in the U.S. marketplace is safe, wholesome, unadulterated, and properly labeled by (1) determining if foreign countries and their establishments have implemented food safety system and inspection requirements equivalent to those in the United States and (2) reinspecting imported meat and poultry products from those countries through random sampling of shipments. The FSIS regulations in 9 CFR 327.2 provide that countries eligible to export meat to the United States must have a meat inspection system determined by FSIS to be equivalent to the U.S. meat inspection system. The FSIS equivalency determination is based on a review of the foreign country's relevant laws and regulations and an on-site audit of the foreign country's inspection system. FSIS has determined that Japan's meat inspection system is equivalent and that Japan is eligible to export meat and meat products to the United States.

Once a country is listed as eligible to export meat and meat products to the United States, it is responsible for certifying individual exporting establishments to FSIS and for providing annual recertification documentation. FSIS regularly conducts on-site audits of the eligible foreign inspection systems to ensure they remain equivalent to the U.S. system.

Other Applicable Requirements under the FMIA

This proposal would also require that the beef meet all other applicable requirements of the FMIA and regulations thereunder (9 CFR chapter III), including the requirements for removal of SRMs and the prohibition on the use of air-injection stunning devices prior to slaughter on cattle from which the beef is derived.

SRM Removal. The FSIS regulations contained in 9 CFR 310.22 provide that establishments are responsible for ensuring that SRMs are completely removed from the carcass,

segregated from edible products, and disposed of in an appropriate manner.[8] Under the FSIS regulations, an establishment must incorporate such procedures into its Hazard Analysis and Critical Control Point (HACCP) plan or in its sanitation standard operating procedures (SOPs) or other prerequisite program. (HACCP is a process control system designed to identify and prevent microbial and other hazards in food production.) These procedures and requirements help to ensure that SRMs are effectively removed and handled in a manner to avoid contamination of the carcass.

As mentioned above, one potential pathway for cross-contamination of muscle tissue of cattle is if potentially infectious tissue debris accumulates in the carcass splitting saw and is transferred to subsequent carcasses. FSIS has developed procedures to verify that cross-contamination of edible tissue with SRMs is reduced to the maximum extent practical in facilities that slaughter cattle, or process carcasses or parts of carcasses of cattle.[9] This includes verification of sanitization procedures for equipment used to cut through SRMs.

Air-injection Stunning. The FSIS regulations in 9 CFR part 313 prohibit the use of captive bolt stunners that deliberately inject compressed air into the cranium of cattle at the end

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[8] See FSIS' interim final rule entitled, "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (Docket No. 03-025IF, 69 FR 1862-1874), published on January 12, 2004, for further information.

[9] See FSIS Notice 10-04.

FSIS. Verification instructions for the interim final rule regarding specified risk materials (SRMs) in cattle). Notice. January 23, 2005. (Available at: http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/9-04.htm).

FSIS. FSIS Technical Service Center: Common BSE Questions and Answers. March 19, 2005. (Available at: http://www.fsis.usda.gov/oa/FAQ/bse_techcenter.htm).

stage of the penetration cycle. This requirement addresses the potential risk posed by the use of air-injection stunning devices, which may force pieces of brain and other CNS tissue into the circulatory system of stunned cattle.

Pithing

This proposal would prohibit the use of pithing processes on the cattle from which the beef is derived. This requirement addresses the potential risk posed by pithing, which may force pieces of brain and other CNS tissue into the circulatory system of stunned cattle.

Certification

We conclude that whole cuts of boneless beef derived from cattle born, raised, and slaughtered in Japan can be safely imported from Japan into the United States, provided the above-mentioned mitigation measures are met, as certified to on an original certificate issued by an authorized veterinary official of the Government of Japan.

International Guidelines on BSE

International guidelines for trade in animal and animal products are developed by the World Organization for Animal Health (formerly known as the Office International des Epizooties (OIE)), which is recognized by the World Trade Organization (WTO) as the international organization responsible for the development of standards, guidelines, and recommendations with respect to animal health and zoonoses (diseases that are transmissible from animals to humans). The OIE guidelines for trade in terrestrial animals (mammals, birds, and bees) are detailed in the Terrestrial Animal Health Code (available on the internet at http://www.oie.int). The guidelines on BSE are contained in Chapter 2.3.13 of the Code and supplemented by Appendix 3.8.4 of the Code.

The 2005 OIE guidelines on BSE provide for three possible BSE classifications for an exporting country, zone, or compartment (referred to below as a region): Negligible risk, controlled risk, and undetermined risk.

The OIE guidelines for negligible risk regions apply to those regions where either (1) there has been no indigenous cases of BSE or any imported cases of BSE have been completely destroyed, or (2) the last indigenous case of BSE was reported more than 7 years ago. In addition, a region may be considered a negligible risk for BSE if it has demonstrated, through an appropriate level of control and audit, that meat-and-bone meal and greaves derived from ruminants have not been fed to ruminants for at least 8 years, among other criteria. Controlled risk regions, in contrast, include regions where an indigenous case of BSE was reported within the last 7 years and regions that cannot demonstrate that a ruminant-to-ruminant feed ban has been in place for at least 8 years. The OIE guidelines for undetermined risk regions apply to those regions that do not meet the recommended criteria for any other category.

The export conditions contained in the OIE guidelines grow increasingly stringent as the status of a region moves from negligible risk through controlled risk to undetermined risk. For controlled risk regions, the OIE guidelines recommend that meat and meat products not contain SRMs and mechanically separated meat from the skull and vertebral column from cattle over 30 months of age, and that the meat and meat products be derived from cattle that received ante-mortem and post-mortem inspections and that the cattle were not subjected to an air-injection stunning or pithing process at slaughter, among other criteria.

The proposed import conditions for whole cuts of boneless beef from Japan, including the requirements that the beef come from an establishment eligible to export meat to the United

States under the FMIA and FSIS regulations, are consistent with the criteria for controlled risk regions. We believe this is appropriate, given that Japan has reported indigenous cases of BSE within the last 7 years and has measures in place to control BSE risks, but these measures have not been in place long enough for Japan to be considered a negligible risk region. More details on the BSE situation in Japan and Japan's actions to protect animal and human health are contained in the risk analysis.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

Under the Animal Health Protection Act of 2002 (7 U.S.C. 8301 et seq.), the Secretary of Agriculture is authorized to promulgate regulations that are necessary to prevent the introduction or dissemination of any pest or disease of livestock into the United States.

This proposed rule would amend the regulations governing the importation of meat and other edible animal products by allowing, under certain conditions, the importation of whole cuts of boneless beef derived from cattle born, raised, and slaughtered in Japan. We are proposing this action in response to a request from the Government of Japan and after conducting an analysis of the risk that indicates that such beef can be safely imported from Japan under the conditions described in this proposal.

In accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis, which is summarized below, regarding the impact of this proposed rule on small

entities.[10] This analysis also serves as our cost-benefit analysis under Executive Order 12866. Based on the information we have, there is no basis to conclude that this rule will result in any significant economic impact on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on the potential effects. In particular, we are interested in determining the number and kinds of small entities that would incur benefits or costs from the implementation of this proposed rule and the economic effect of those benefits and costs.

This proposal would allow the importation of whole cuts of boneless beef derived from cattle that were born, raised, and slaughtered in Japan, provided that certain conditions are met. We expect that this proposal would have little or no economic impact on the majority of consumers and beef producers in the United States because the volume of beef imported from Japan is likely to be small and have only a minor impact on the overall domestic beef market.

In 2001, APHIS placed a ban on the importation of ruminants and most ruminant products from Japan following the confirmation of one case of BSE in a native-born animal in that country. Prior to that ban, U.S. imports of boneless beef from Japan were negligible when compared to total imports of that commodity. Over the 4-year period, 1997-2000, for example, the volume of U.S. imports of boneless beef from Japan—reported to be entirely fresh/chilled, as opposed to frozen—averaged a little less than 9 metric tons per year. This amount was less than 0.005 percent of average annual U.S. imports of fresh/chilled boneless beef world-wide for the

[10] A copy of the full economic analysis is available for review on EDOCKET or in our reading room. (Information on accessing EDOCKET as well as the location and hours of the reading room may be found at the beginning of this document under ADDRESSES.)

same period (202,540 metric tons).[11] The average annual value of U.S. imports of boneless beef from Japan over this 4-year period was $808,000, less than 0.2 percent of the 4-year average annual value of U.S. imports of fresh/chilled boneless beef from all regions ($600 million). Including frozen boneless beef in the comparison over the same 4-year period diminishes Japan's annual average percentage share all the more, to about 0.001 percent of the quantity and about 0.05 percent of the value of all U.S. boneless beef imports. This impact would be further reduced if Japan's share of the U.S. total beef supply (domestic production plus imports minus exports, disregarding carryover stocks) were considered.

Based on the unit price of beef imported into the United States from Japan prior to the 2001 ban on the importation of ruminants and most ruminant products from Japan, it is assumed that all of the boneless beef imported from Japan prior to the ban was Wagyu beef. (The term "Wagyu," which literally translates to Japanese cattle, refers to purebred Japanese Black or Japanese Brown breeds of cattle. Wagyu beef is a high-priced specialty meat widely acclaimed for its flavor and tenderness. "Kobe beef" refers to Wagyu beef that is produced in the Kobe area of Japan.) Japan also produces Holstein breed dairy cattle, but it is unlikely that Japan would try to compete in the U.S. import market for lower-grade beef from culled dairy cattle. Accordingly, we expect only Wagyu beef to be imported under the proposed rule.

We expect that Japan would continue to be a minor supplier of beef to the United States if this proposal were adopted. We estimate that the volume of imports is likely to range between

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[11] Trade statistics, unless otherwise indicated, are taken from the World Trade Atlas or the Global Trade Atlas (Global Trade Information Services), which report data from the Department of Commerce, U.S. Bureau of the Census. The Harmonized Tariff Schedule (HTS) 6-digit code for fresh/chilled boneless beef cuts is 020130; the HTS code for frozen boneless beef is 020230.

about 8 metric tons and 15 metric tons per year, a quantity aligned with import levels in the years immediately prior to the ban. There are three reasons for the small import volume. First, the demand for Japanese Wagyu beef in the United States would likely be small, because the beef is expensive. In October 2004, for example, the average actual selling price of Wagyu sirloin in Japanese supermarkets was just under $50 per pound.[12] The price of Japanese Wagyu beef would be higher in the United States because of transportation and other costs associated with the importation of the beef from Japan.

Second, Japanese agricultural officials have indicated to APHIS staff that they would expect the volume of Wagyu exports to the United States to be approximately 10 metric tons per year. This quantity aligns with historic import levels, as described above, and would be well below the annual tariff rate quota for Japan of 200 metric tons.[13] Over the 10-year period from 1991 to 2000 U.S. imports of boneless beef—both fresh/chilled and frozen—from Japan never exceeded 27.0 metric tons in any one year.

Finally, Japan's boneless beef exports to countries other than the United States have also been minor. Over the 4-year period 1997-2000, Japan's exports of boneless beef to the world–both fresh/chilled and frozen–averaged only 81 metric tons per year, and the largest export

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[12] Source: "Monthly Statistics," January 2005, Agricultural & Livestock Industries Corporation. The selling price was calculated using an exchange rate of 105 yen per U.S. dollar and it is the price for Wagyu sirloin from all regions in Japan, including Kobe.

[13] Harmonized Tariff Schedule of the United States (2005), Chapter 2, Meat and Edible Meat Offal.

volume in any one of those years was 95 metric tons (in 1999). For fresh/chilled boneless beef alone, the 4-year annual average was 37 metric tons, with no one year exceeding 47 metric tons.[14]

Because we expect that Japan would export only Wagyu beef if this proposal were adopted, this action has the potential to affect farmers and ranchers in the United States who raise Wagyu and Wagyu hybrid cattle for the high-end domestic beef market. However, the impact, if any, on these so-called "Kobe-style" beef producers is unclear, without an approximation of the quantity of Kobe-style beef sold in the United States and information on the extent to which the two products would directly compete. The number of these producers is unknown, but it is believed to be very small.

Cost-Benefit Analysis

Given the high price and small quantity of Wagyu beef expected to be imported, the proposed rule is likely to have little impact for most U.S. consumers. A relatively small segment of beef consumers would benefit because they would be allowed, once again, to buy this product in the United States. Importers, brokers and others in the United States who would participate in the importation of Wagyu beef from Japan also stand to benefit, due to the increased business activity.

U.S. beef producers, in general, would not be affected by the proposed rule; demand is expected to remain low reflecting pre-ban consumption patterns, with a minor impact on less expensive domestically produced beef. Any producer impact of the rule would likely fall upon producers of Kobe-style beef, and then only to the extent that the commodities would be competing for the same niche market.

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[14] Foreign Agricultural Service, USDA.

In general, trade of a commodity increases social welfare. To the extent that consumer choice is broadened and the increased supply of the imported commodity leads to a price decline, gains in consumer surplus will outweigh losses in domestic producer surplus.[15] Although the rule's impact on the relatively small number of U.S. producers of Kobe-style beef is uncertain, it is expected to provide benefits to consumers (domestic importers, wholesalers, retailers, as well as final consumers) that would exceed any potential losses to domestic producers. The net welfare effect for the United States of reestablished Wagyu beef imports from Japan would be positive.

Effects on Small Entities

We do not expect that this proposal would have significant economic impact on a substantial number of small entities. As discussed above, the proposed rule has the potential to primarily affect farmers and ranchers in the United States who produce Kobe-style beef. The number of these producers is unknown, but it is believed to be very small. The American Wagyu Association, a Wagyu breeder group, lists approximately 75 members in the United States.[16]

The size distribution of Kobe-style beef producers in the United States is also unknown, but it is reasonable to assume that most are small, under the U.S. Small Business Administration's (SBA) standards. This assumption is based on composite data for all beef producers in the United States. In 2002, there were 664,431 U.S. farms in North American Industry Classification System (NAICS) 112111, a classification comprised of establishments

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[15] Consumer surplus is the difference between the amount a consumer is willing to pay for a good and the amount actually paid. Producer surplus is the amount a seller is paid for the good minus the seller's cost.

[16] Source: American Wagyu Association web site.

primarily engaged in raising cattle. Of the 664,431 farms, 659,009 (or 99 percent) had annual receipts that year of less than $500,000.[17] The SBA's small entity threshold for farms in NAICS 112111 is annual receipts of $750,000.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the proposed importation of whole cuts of boneless beef from Japan, we have prepared an environmental assessment. The environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment may be viewed on the EDOCKET Web site (see ADDRESSES above for instructions for accessing EDOCKET) or on the APHIS Web site at http://www.aphis.usda.gov/lpa/issues/bse/bse.html. You may request paper copies of the

[17] 2002 Census of Agriculture, National Agricultural Statistics Service.

environmental assessment by calling or writing to the person listed under FOR FURTHER INFORMATION CONTACT. Please refer to the title of the environmental assessment when requesting copies. The environmental assessment is also available for review in our reading room (information on the location and hours of the reading room is provided under the heading ADDRESSES at the beginning of this notice).

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 would continue to read as follows:

Authority: 7 U.S.C. 450, 7701-7772, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. In § 94.18, paragraph (b) would be revised to read as follows:

§ 94.18 Restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy.

* * * * *

(b) Except as provided in paragraph (d) of this section or in §§ 94.19 or 94.27, the importation of meat, meat products, and edible products other than meat (except for gelatin as provided in paragraph (c) of this section, milk, and milk products) from ruminants that have been in any of the regions listed in paragraph (a) of this section is prohibited.

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3. A new § 94.27 would be added to read as follows:

§ 94.27 Importation of whole cuts of boneless beef from Japan.

Notwithstanding any other provisions of this part, whole cuts of boneless beef derived from cattle that were born, raised, and slaughtered in Japan may be imported into the United States under the following conditions:

(a) The beef is prepared in an establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the regulations in 9 CFR 327.2 and the beef meets all other applicable requirements of the Federal Meat Inspection Act and regulations thereunder (9 CFR chapter III), including the requirements for removal of SRMs and the prohibition on the use of air-injection stunning devices prior to slaughter on cattle from which the beef is derived.

(b) The beef is derived from cattle that were not subjected to a pithing process at slaughter.

(c) An authorized veterinary official of the Government of Japan certifies on an original certificate that the above conditions have been met.

Done in Washington, DC, this 15th day of August, 2005.

/s/ W. Ron DeHaven

Acting Under Secretary for Marketing and Regulatory Programs.